

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Previously Presented): A method for the treatment of cancer within a patient, comprising administering to said patient an effective amount of troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours wherein a steady state plasma concentration of troxacitabine of 0.03 to 2.0  $\mu$ M is achieved during the administration,

wherein said cancer is lung cancer, prostate cancer, bladder cancer, colorectal cancer, pancreatic cancer, renal cancer, hepatoma, gastric cancer, breast cancer, ovarian cancer, soft tissue sarcoma, osteosarcoma, hepatocellular carcinoma, skin cancer, leukemia or lymphoma.

2. (Cancelled):

3. (Previously Presented): A method according to claim 1, wherein said cancer is pancreatic cancer.

4. (Previously Presented): A method according to claim 1, wherein said cancer is leukemia selected from acute myelogenous leukemia, chronic myelogenous leukemia, chronic myelogenous leukemia in blastic phase, and refractory myelodysplastic syndromes.

5. (Original): A method according to claim 4, wherein said cancer is acute myelogenous leukemia.

6. (Previously Presented): A method according to claim 1, wherein a steady state plasma concentration of 0.05 to 0.1  $\mu$ M is achieved during the administration.

7. (Original): A method according to claim 4, wherein a steady state plasma concentration of 0.1 to 0.42  $\mu$ M is achieved during the administration.

8. (Previously Presented): A method for the treatment of cancer within a patient, comprising administering to said patient an effective amount of troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours, wherein the maximum plasma concentration achieved during the administration is 0.03 to 2.0  $\mu$ M,

wherein said cancer is lung cancer, prostate cancer, bladder cancer, colorectal cancer, pancreatic cancer, renal cancer, hepatoma, gastric cancer, breast cancer, ovarian cancer, soft tissue sarcoma, osteosarcoma, hepatocellular carcinoma, skin cancer, leukemia or lymphoma.

9. (Previously Presented): A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is 0.03  $\mu$ M to less than 1.0  $\mu$ M.

10. (Previously Presented): A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is 0.03  $\mu$ M to less than 0.5  $\mu$ M.

11. (Previously Presented): A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is 0.03  $\mu$ M to less than 0.42  $\mu$ M.

12. (Previously Presented): A method according to claim 8, wherein the maximum plasma concentration achieved during the administration is 0.03  $\mu$ M to less than 0.1  $\mu$ M.

13. (Previously Presented): A method for the treatment of cancer within a patient, comprising administering to said patient troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours at a dose of 0.72 to 12.5 mg/m<sup>2</sup>/day,

wherein said cancer is lung cancer, prostate cancer, bladder cancer, colorectal cancer, pancreatic cancer, renal cancer, hepatoma, gastric cancer, breast cancer, ovarian cancer, soft

tissue sarcoma, osteosarcoma, hepatocellular carcinoma, skin cancer, leukemia or lymphoma.

14. (Original): A method according to claim 13, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 1.0 to 11.0 mg/m<sup>2</sup>/day.

15. (Original): A method according to claim 13, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 8.0 to 11.0 mg/m<sup>2</sup>/day.

16. (Cancelled):

17. (Previously Presented): A method according to claim 13, wherein said cancer is pancreatic cancer.

18. (Previously Presented): A method according to claim 13, wherein said cancer is leukemia selected from acute myelogenous leukemia, chronic myelogenous leukemia, chronic myelogenous leukemia in blastic phase, and refractory myelodysplastic syndromes.

19. (Original): A method according to claim 18, wherein said cancer is acute myelogenous leukemia.

20. (Previously Presented): A method according to claim 13, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 3.0 mg/m<sup>2</sup>/day.

21. (Original): A method according to claim 13, wherein said cancer is a solid tumor and the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 2.5mg/m<sup>2</sup>/day.

22. (Original): A method according to claim 18, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof 9.5 to 10.5mg/m<sup>2</sup>/day.

23. (Previously Presented): A method according to claim 1, wherein said continuous infusion is administered for a period of 3 to 7 days.

24. (Previously Presented): A method according to claim 1, wherein said continuous infusion is administered for a period of 3 days.

25. (Previously Presented): A method according to claim 1, wherein said continuous infusion is administered for a period of 4 days.

26. (Previously Presented): A method according to claim 1, wherein said continuous infusion is administered for a period of 5 days.

27. (Previously Presented): A method according to claim 1, wherein said continuous infusion is administered for a period of 6 days.

28. (Previously Presented): A method according to claim 1, wherein said continuous infusion is administered for a period of 7 days.

29. (Previously Presented): A method according to claim 13, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 2.5mg/m<sup>2</sup>/day, said period is 3 days, and a steady state plasma concentration of 0.05 to 0.1 µM of troxacitabine or a pharmaceutically acceptable salt thereof is achieved during the administration.

30. (Previously Presented): A method according to claim 13, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 2.0 to 2.5mg/m<sup>2</sup>/day, said period is 4 days, and a steady state plasma concentration of 0.05 to 0.1 µM of troxacitabine or a pharmaceutically acceptable salt thereof is achieved during the administration.

31. (Original) A method according to claim 18, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 9.5 to 10.5mg/m<sup>2</sup>/day, said period is 5 days, and a steady state plasma concentration of 0.1 to 0.42  $\mu$ M of troxacitabine or a pharmaceutically acceptable salt thereof is achieved during the administration.

32. (Original): A method according to claim 18, wherein the dosage amount of troxacitabine or a pharmaceutically acceptable salt thereof is 9.5 to 10.5mg/m<sup>2</sup>/day, said period is 6 days, and a steady state plasma concentration of 0.1 to 0.42  $\mu$ M of troxacitabine or a pharmaceutically acceptable salt thereof is achieved during the administration.

33. (Previously Presented): A method according to claim 1, further comprising repeating said continuous infusion at an interval of every 4 weeks.

34. (Previously Presented): A method according to claim 1, further comprising repeating said continuous infusion at an interval of every 3 weeks.

35. (Previously Presented): A method according to claim 1, further comprising repeating said continuous infusion at an interval of every 5 weeks.

36. (Previously Presented): A method according to claim 1, wherein said continuous infusion is by means of continuous intravenous infusion.

37. (Previously Presented): A method according to claim 1, wherein said method further comprises, in combination with said continuous administration of troxacitabine, administering at least one further therapeutic agent selected from nucleoside analogues; chemotherapeutic agents; multidrug resistance reversing agents; and biological response modifiers.

38. (Previously Presented): A method according to claim 37, wherein said at least one further therapeutic agent is a chemotherapeutic agent selected from Asparaginase, Bleomycin, Busulfan, Carmustine, Chlorambucil, Cladribine, Cyclophosphamide, Cytarabine,

Dacarbazine, Daunorubicin, Doxorubicin, Etoposide, Fludarabine, Gemcitabine, imatinib mesylate, Hydroxyurea, Idarubicin, Ifosfamide, Lomustine, Mechlorethamine, Melphalan, Mercaptopurine, Methotrexate, Mitomycin, Mitoxantrone, Pentostatin, Procarbazine, 6-Thioguanine, Topotecan, Vinblastine, Vincristine, Dexamethasone, Retinoic acid and Prednisone.

39. (Original): A method according to claim 37, wherein said at least one further therapeutic agent is the multidrug resistance reversing agent PSC 833.

40. (Original): A method according to claim 37, wherein said at least one further therapeutic agent is a biological response modifier selected from monoclonal antibodies and cytokines.

41. (Previously Presented): A method according to claim 40, wherein said at least one further therapeutic agent is a cytokine selected from interferons, interleukins and colony-stimulating factors.

42. (Original): A method according to claim 37, wherein said at least one further therapeutic agent is a biological response modifier selected from Rituxan, CMA-676, Interferon-alpha recombinant, Interleukin-2, Interleukin-3, Erythropoetin, Epoetin, G-CSF, GM-CSF, Filgrastim, Sargramostim and Thrombopoietin.

43. (Previously Presented): A method according to claim 37, wherein said troxacitabine or a pharmaceutically acceptable salt thereof and said at least one further therapeutic agent are administered sequentially.

44. (Previously Presented): A method according to claim 37, wherein said troxacitabine or a pharmaceutically acceptable salt thereof and at least one further therapeutic agent are administered simultaneously.

45. (Previously Presented): A method according to claim 44, wherein said

troxacitabine or a pharmaceutically acceptable salt thereof and at least one further therapeutic agent are administered in separate pharmaceutical formulations.

46. (Previously Presented): A method according to claim 44, wherein said troxacitabine or a pharmaceutically acceptable salt thereof and at least one further therapeutic agent are administered in combined pharmaceutical formulations.

47. (Original): A method for the administration of troxacitabine or a pharmaceutically acceptable salt thereof in a host having a tumor, comprising administering an amount of troxacitabine or a pharmaceutically acceptable salt thereof by continuous infusion for a period of at least 72 hours, wherein said amount is sufficient to provide tumor reduction.

48. (Previously Presented): A method according to claim 8, wherein said cancer is pancreatic cancer.

49. (Previously Presented): A method according to claim 8, wherein said cancer is leukemia selected from acute myelogenous leukemia, chronic myelogenous leukemia, chronic myelogenous leukemia in blastic phase, and refractory myelodysplastic syndromes.

50. (Previously Presented): A method according to claim 49, wherein said cancer is acute myelogenous leukemia.

51. (Previously Presented): A method according to claim 8, wherein said continuous infusion is by means of continuous intravenous infusion.

52. (Previously Presented): A method according to claim 8, wherein said method further comprises, in combination with said continuous administration of troxacitabine, administering at least one further therapeutic agent selected from nucleoside analogues; chemotherapeutic agents; multidrug resistance reversing agents; and biological response modifiers.

53. (Previously Presented): A method according to claim 52, wherein said at least one further therapeutic agent is a chemotherapeutic agent selected from Asparaginase, Bleomycin, Busulfan, Carmustine, Chlorambucil, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin, Etoposide, Fludarabine, Gemcitabine, imatinib mesylate, Hydroxyurea, Idarubicin, Ifosfamide, Lomustine, Mechlorethamine, Melphalan, Mercaptopurine, Methotrexate, Mitomycin, Mitoxantrone, Pentostatin, Procarbazine, 6-Thioguanine, Topotecan, Vinblastine, Vincristine, Dexamethasone, Retinoic acid and Prednisone.

54. (Previously Presented): A method according to claim 13, wherein said cancer is pancreatic cancer.

55. (Previously Presented): A method according to claim 13, wherein said continuous infusion is by means of continuous intravenous infusion.

56. (Previously Presented): A method according to claim 13, wherein said method further comprises, in combination with said continuous administration of troxacicabine, administering at least one further therapeutic agent selected from nucleoside analogues; chemotherapeutic agents; multidrug resistance reversing agents; and biological response modifiers.

57. (Previously Presented): A method according to claim 56, wherein said at least one further therapeutic agent is a chemotherapeutic agent selected from Asparaginase, Bleomycin, Busulfan, Carmustine, Chlorambucil, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin, Etoposide, Fludarabine, Gemcitabine, imatinib mesylate, Hydroxyurea, Idarubicin, Ifosfamide, Lomustine, Mechlorethamine, Melphalan, Mercaptopurine, Methotrexate, Mitomycin, Mitoxantrone, Pentostatin, Procarbazine, 6-Thioguanine, Topotecan, Vinblastine, Vincristine, Dexamethasone, Retinoic acid and Prednisone.

58. (Previously Presented): A method according to claim 47, wherein said continuous infusion is by means of continuous intravenous infusion.

59. (Previously Presented): A method according to claim 47, wherein said method further comprises, in combination with said continuous administration of troxacicabine, administering at least one further therapeutic agent selected from nucleoside analogues; chemotherapeutic agents; multidrug resistance reversing agents; and biological response modifiers.

60. (Previously Presented): A method according to claim 59, wherein said at least one further therapeutic agent is a chemotherapeutic agent selected from Asparaginase, Bleomycin, Busulfan, Carmustine, Chlorambucil, Cladribine, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin, Etoposide, Fludarabine, Gemcitabine, imatinib mesylate, Hydroxyurea, Idarubicin, Ifosfamide, Lomustine, Mechlorethamine, Melphalan, Mercaptopurine, Methotrexate, Mitomycin, Mitoxantrone, Pentostatin, Procarbazine, 6-Thioguanine, Topotecan, Vinblastine, Vincristine, Dexamethasone, Retinoic acid and Prednisone